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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,405	11/30/2004	Wolfgang Demmer	9013.0099	2828

7590 09/14/2009

Attn: Dennis E. Stenzel, Esq.
Chernoff, Vilhauer, McClung & Stenzel, LLP
Suite 1600
601 S.W. Second Avenue
Portland, OR 97204-3157

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,405	DEMMER ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009 and 15 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments filed May 11, 2009, and June 15, 2009, have been received and entered.

Claims 1-10, 12, 13, and 16 are cancelled. Claims 11, 14, and 15 are pending and examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grano et al. (International Journal of Artificial Organs, 2002, 25(4): 297-305) in view of Sugo et al. (US 5,071,880), Sigma Aldrich (http://www.sigmaaldrich.com, accessed on 9/3/09 and 9/9/09), Chemical Book (http://www.chemicalbook.com, accessed on 9/3/09), Organische

Chemie (Carey et al., 1995, Plenum Publishing Corporation, page 1390), Advanced Organic Chemistry (March, J., 3rd edition, 1985, John Wiley & Sons, Inc., page 369), and Burtin et al. (US 6,248,238).

Grano et al. discloses a membrane loaded with antiproteases for reducing the active protease blood concentration (abstract), wherein a protease/antiprotease complex is formed upon contacting the membrane with a solution containing proteases (page 298, first column, first paragraph). An antitrypsin is immobilized via diazotization occurring through tyrosine residues (page 299, first column, first full paragraph and Figure 1). Thus, the protease inhibitor (antitrypsin) is coupled to the membrane body via functional groups, where nonionic chemical bonding occurs. Further still, it is noted that trypsin is a serine protease (page 300, second column, second paragraph under "Results").

Grano et al. does not expressly disclose that the antiprotease loaded on the membrane is pepstatin, bestatin, diprotin, antipain, chymostatin, leupeptin, E64, TLCK, or p-aminobenzamidine, where the antiprotease is chemically coupled to epoxy groups of the membrane which is epoxy-functionalized and microporous.

It is noted that Grano et al. teaches that the membrane for loading with antiproteases is grafted with glycidyl methacrylate (page 298, first column, last sentence). This membrane is a "Supor" R/polyGMA membrane (page 293, second column, fourth full paragraph).

Sugo et al. teaches that glycidyl methacrylate is an epoxy-containing polymerizable monomer (column 3, lines 29-31 and column 1, line 67 through column 2, line 1).

The references Sigma Aldrich and Chemical Book demonstrate that the protease inhibitors recited in instant claim 11 have primary and/or secondary amine groups.

Organische Chemie and Advanced Organic Chemistry demonstrate that primary and secondary amine groups react with epoxy groups to chemically couple the respective moieties containing the epoxy and amine groups.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used the Grano "Supor" R/polyGMA membrane to bind protease inhibitors, including pepstatin, bestatin, diprotin, antipain, chymostatin, leupeptin, E64, TLCK, and p-aminobenzamidine, when practicing the Grano invention in order to serve the purpose of the Grano invention to reduce protease concentrations. One of ordinary skill in the art would have been motivated to do this in order to have removed a variety of proteases, or to have ensured that a specific protease is indeed removed. There would have been a reasonable expectation of success that the Grano membrane would have bound to those protease inhibitors since those protease inhibitors have amine groups which would have chemically coupled to the epoxy groups known to be present in the glycidyl methacrylate grafted on the Grano membranes.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used different compounds as the protease inhibitors present in the membranes of the device, where the different compounds may be present in different membranes and/or combined with other protease inhibitors in the same membrane. One of ordinary skill in the art would have been motivated to do this in order to have separated a variety of proteases from a solution, or to have ensured that a specific protease is indeed separated from a solution. It would have been obvious to have used compounds recognized in the art as protease inhibitors, including those recited in instant claim 11, in the device, as Grano et al. does not limit the protease inhibitor included in its membranes.

Grano et al. also differs from the claimed invention in that it does not expressly disclose a device having a housing with a fluid inlet and a fluid outlet comprising a plurality of membranes.

Burtin et al. discloses a medical apparatus for the extracorporeal treatment of blood or plasma, comprising a semi-permeable membrane with protease inhibitors (column 4, lines 34-36). The apparatus clearly comprises a housing having a fluid inlet and a fluid outlet (see Figure 5).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used the Grano membranes in a series in a medical apparatus for the extracorporeal treatment of blood. One of ordinary skill in the art would have been motivated to do this since Burtin et al. demonstrates that protease inhibitors on membranes in a housing with a fluid inlet and a fluid outlet is suitable for treatment of blood. Further more, the use of multiple membranes in a series would have ensured thorough reduction of the active protease blood concentration. Thus, instant claims 11, 14, and 15 are rendered obvious.

Response to Arguments

Applicant's arguments filed May 11, 2009 and June 15, 2009, have been fully considered but they are not persuasive. The applicant asserts that it is well known that primary and secondary amine groups react with epoxy groups to chemically couple the respective moieties containing the epoxy and amine groups. Given the evidence provided by the applicant, the Organische Chemie and Advanced Organic Chemistry references have been introduced in the rejection along with the teaching that the Grano invention provides a membrane with epoxy groups.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef